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INDUSTRIAL
biotechnology



GAIKER

TECHNOLOGY CENTRE



BIOTECHNOLOGY AREA

In GAIKER, the Biotechnology area is focused to integrally cover the particular needs of innovation and control for our clients' production processes, from the very beginning of the process to the actual quality and standardisation of the final product.

To reach this goal, we have five types of application technologies as tools:

- **Molecular Biology**
- **Cellular Culturing**
- **Functional Genomics**
- **Industrial Microbiology**
- **Enzymatic Applications**

Based on the requirements of each of our customers, mostly from pharmaceutical, cosmetic, chemical and food and agriculture sectors, we use the most suitable of the technologies.

Our wide experience in tailored developments, based on the application of these technologies, allows us to offer services in which quality is our main and permanent priority.

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- **Studies with GLP guarantee**
 - **ISO 9001 quality systems**

The quality of our studies in GAIKER, together with our most advanced services, is the highest. We are committed to the quality and to achieve that, we have in our hands the greatest technology and our most valuable asset, which is a specialised and committed staff.



WE GUARANTEE our services

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All our services in GAIKER have a common factor: Quality. International protocol of Good Laboratory Practises (GLP) and the project management under ISO 9001 quality systems vouch **our services**:

Effectiveness of active principle assessment through the combined use of models of cellular culturing and studies on genes involved in the metabolic reaction.

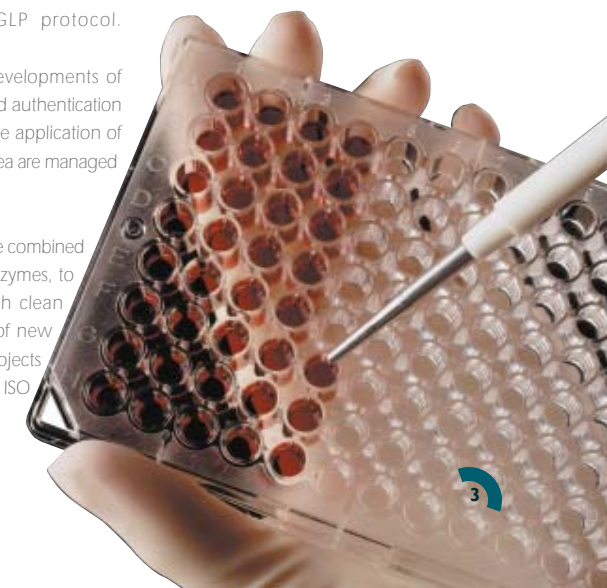
Pharmacokinetic studies of active principles using models of specific cellular lines and/or cellular fractions supported by the instrumental detection of the substrate product transformation.

Toxicological studies supported on "in vitro" cellular models. Studies are carried out under the GLP protocol.

In **Food Safety**, we carry out tailored developments of detection systems of emergent pathogens and authentication of raw on transformed products, through the application of molecular biology techniques. Projects in this area are managed under the ISO 9001 rule.

As far as **Bioprocesses** are concerned, we use combined techniques of industrial microbiology and enzymes, to improve the production processes through clean technologies, as well as the development of new products of the BIO line. Management of projects in this field of application is supported by the ISO 9001 quality system.

The project management under ISO 9001 quality systems vouch our services





OUR MOST ADVANCED SERVICES

Besides our studies guarantee, in GAIKER we offer a wide range of Advanced Services also characterised for having as a priority objective the achievement of the highest quality.

Characterisation of raw materials and final product

For us to be able to offer these services we use the most advanced tooling techniques. We count on methodologies of fast detection and fraud identification on raw materials and we never compromise the quality of our final product. With this purpose, we put in practise molecular biology techniques (PCR, PCR- ELISA, quantitative RT- PCR), cellular culturing, gas chromatography, gas/mass gas fitted to "sniffing" detector, liquid chromatography HPLC, HPLS-masses, FPLC, TLC, infrared (FT- IR) and ICP.

In our infrastructures we have level 2 (P2) and 3 (P3) risk contention laboratories.

The most advanced services GAIKER can offer in the Biotechnology area are:

- Specific development of authentication techniques of raw materials on final product.
- Detection of transgenic material in raw materials/product.
- ADME⁽¹⁾ studies.
- Microbiotic characterisation.
 - Quantification and detection of the focus of pollution.
 - Detection and quantification of pathogens.
 - Establishment of purity and viability of target culture.

- Characterisation of the effectiveness of ingredients/ formulations. Product effectiveness (GLP).
 - Evaluation of physiological effects specific to each organ, through the culturing of cell lines and the combined applications of subtraction gene factors, RT-PCR.
 - Anti-inflammatory effects.
 - Anti-ageing effects: free radicals, based on studies of the DNA's integrity, sequence of amino acids in proteins, anti-elastasic activity.
 - Evaluated photo-protection on culturing of human cell lines.
 - Skin protection. Anti-pollution effects.
 - Restoration-Healing effects: Collagen.
 - Stimulation of cell growth.
 - Effects on pigmentation.
- Evaluation of Sanitary risks:
 - Establishment of mutagenic profiles. Genical mutation on bacterias and cells of mammals, cytogenetic tests.
 - Studies on toxicological profiles: Cytotoxicity, dermic and ocular irritation, photo-toxicity.
 - Studies on biocompatibility of materials for sanitary use.
 - Comparative studies of the toxicity level of raw materials in order to select the most suitable ones for the formulation of a product.
 - Studies on the toxicity level of products/raw materials on primary culturing of cell lines.
 - Establishment of the most suitable set of In Vitro tests in order to preliminary determine the toxicity level of products.
- Physio-chemical characterisation:
 - Concentration analysis, purity, solvents' trace analysis.
 - Detection of contaminants in raw materials and processes, non-compliant products: pesticides, chlorinated compounds, fats, solvents, hydrocarbons, analysis of metals, aflatoxins, sulphamides.

- Biochemical characterisation:
 - Nutritious value, vitamins, amino acids, fats, oils and fatty acids, sugars and sweetening, peptides and proteins.
 - Characterisation of the activity and suitability of enzymatic compounds.
- Approval of analytic methods.



Production

PROCESSES

- Production processes - Study of viability of clean technologies.

GAIKER develops new processes which use enzymes and/or microorganisms, as well as the substitution of chemical processes by enzymatic processes in which we evaluate, apart from the technical viability of the process, the economic viability, comparing it with the existing process.

- Search and study of existing enzymes and selection of the most suitable one or/and blend for each specific reaction.
- Optimisation of reaction conditions to get the highest performance at the lowest cost.
- Establishment of the optimised solution on the pilot plant.
- Support on the system's industrial application.

- Implementation of hygiene control systems on plants.

We establish the basis for the elaboration of a cleaning and hygienic programme in order to reduce and control the contamination risk related to the production infrastructure.

- Separation and purification processes of a chemical product.

The separation and purification of a product is a critical stage in many processes. We base our offer on processes such as: filtration (including micro-filtration and ultra-filtration by membranes), centrifugation and chromatographic separation (indicated for macromolecules), extraction by super-critical fluids, etc. We select the most suitable processes and we optimise the existing ones, both at laboratory and pilot plant levels.

Our target is to deserve our customers' trust

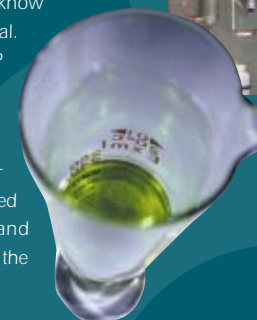


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In all, our target is to have our customers' trust and we know how to achieve this goal. Both our studies with GLP Guarantee and our

Advanced Studies have the constant and common objective of achieving quality and the highest tailoring of our work to their needs. We offer personalised services elaborated by specialised and experienced staff for whom we provide the most advanced technology.



Our Advanced Services have the constant and common objective of achieving quality and the highest tailoring of our work to our customers' needs

